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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,335	12/03/2003	David J. Hammond	2308/660	5513

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,335	HAMMOND ET AL.	
	Examiner	Art Unit	
	AGNIESZKA BOESEN	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/28/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,13,14,20-37 and 40-45* is/are pending in the application.

4a) Of the above claim(s) *20-35,40, 41 43 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,13,14,36,37,42 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/15/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed October 1, and December 28, 2007 in response to the Office Action May 30, 2007 is acknowledged and has been entered.

Claims 2, 9, 38 and 39 have been canceled. New claims 43-45 have been added. Claims 1, 3, 4, 13, 14, 36, 37, 42 and 45 are under examination in this Office action. It is noted that withdrawn claims 36 and 37 are rejoined.

Election/Restriction

Newly submitted claims 43 and 44 are directed to an invention that is independent or distinct from the invention originally claimed for the reasons stated below. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. The invention of the group I below has been examined in the action on the merits of May 30, 2007, and therefore claims 1, 3, 4, 13, 14, 42, and 45, directed to the invention of group I are presently examined. Accordingly, new claims 43 and 44 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

I. Claims 1, 3, 4, 13, 14, 36, 37, 42, and 45 drawn to a prion ligand capable of binding to a peptide, classified in class 530, subclass 300.

II. Claims 43 and 44, drawn to a method of detecting and removing a prion protein in a sample, classified in class 435, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of detecting and removing a prion protein can be practiced with another materially different product. The detection and removing of a prion protein can be practiced using an antibody specific to the prion molecule in an immunoassay. Additionally the two distinct inventions have acquired different status in the art as shown by their different classification. Literature search regarding the method of detecting the prion molecule will not necessarily reveal the information regarding the prion ligand. Furthermore searching all amino acid sequences together would be a serious search burden on the Office.

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

Rejection of claims 1, 3 and 4 under 35 U.S.C. 112, first paragraph, **is withdrawn** in view of Applicant's amendment.

Rejection of claims 1, 3 and 4 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

Rejection of claims 1 and 2 under 35 U.S.C. 102(a)and 102(e) as being anticipated by Chesebro et al. (US Patent 6,355,610 B2) **is withdrawn** in view of Applicant's amendment.

New Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Venter et al. (WO 200171042-A2) as evidenced by Chesebro et al. (US Patent 6,355,610 B2).

Venter discloses a sequence comprising present SEQ ID NO: 5 (see SEQ ID NO: 20151, it is noted that the WO 200171042-A2 document is attached to the present Office action however because the document containing the sequence listing for the WO 200171042-A2 is very large Applicant is requested to look up the sequence listing on the WIPO website, Examiner provides the search results below for present SEQ ID NO: 5 below). It is noted that the claims recite an open claim language with regard to the sequences. Claim 4 reciting "the ligand has six amino acids" is interpreted as reciting an open claim language with regard to the sequences because the claim recites "the ligand has six amino acids". Claim 4 is interpreted to mean that the ligand has at least six amino acids. Verner's sequence has at least six amino acids. Because Verner's sequence comprises the claimed ligans of SEQ ID NO: 5, Verner's sequence would be expected to bind to the prion peptide having the amino acid sequence of present SEQ ID NO: 1. Chesebro

is cited as an evidence reference because Chesebro discloses that the present SEQ ID NO: 1 (RYPGQ or Arg Tyr Pro Gly Gln) is comprise in the prion protein (see column 3, lines 18-57, column 7, lines 35-54, Example 11, particularly line 14, and SEQ ID NO: 18-22). Thus by this disclosure Verner anticipates the present claims.

```
DE   Drosophila melanogaster polypeptide SEQ ID NO 20151.
XX
KW   Drosophila; developmental biology; cell signalling; insecticide;
KW   pharmaceutical.
XX
OS   Drosophila melanogaster.
XX
PN   WO200171042-A2.
XX
PD   27-SEP-2001.
XX
PF   23-MAR-2001; 2001WO-US009231.
XX
PR   23-MAR-2000; 2000US-0191637P.
PR   11-JUL-2000; 2000US-00614150.
XX
PA   (PEKE ) PE CORP NY.
XX
PI   Venter JC,  Adams M,  Li PWD,  Myers EW;
XX
DR   WPI; 2001-656860/75.
DR   N-PSDB; ABL08556.
XX
PT   New isolated nucleic acid detection reagent for detecting 1000 or more
PT   genes from Drosophila and for elucidating cell signaling and cell-cell
PT   interactions.
XX
PS   Disclosure; SEQ ID NO 20151; 21pp + Sequence Listing; English.
XX
CC   The invention relates to an isolated nucleic acid detection reagent
CC   capable of detecting 1000 or more genes from Drosophila. The invention
is
CC   useful in developmental biology and in elucidating cell signalling and
CC   cell-cell interactions in higher eukaryotes for the development of
CC   insecticides, therapeutics and pharmaceutical drugs. The invention
CC   discloses genomic DNA sequences (ABL16176-ABL30511), expressed DNA
CC   sequences (ABL01840-ABL16175) and the encoded proteins (ABB57737-
CC   ABB72072). The sequence data for this patent did not form part of the
CC   printed specification, but was obtained in electronic format directly
CC   from WIPO at ftp.wipo.int/pub/published_pct_sequences
XX
SQ   Sequence 216 AA;
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  Query Match             100.0%;  Score 36;  DB 4;  Length 216;
  Best Local Similarity   100.0%;  Pred. No. 25;
  Matches    7;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 KIHKFLA 7
              |||||||
Db        102 KIHKFLA 108
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Claims 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill (US Patent 5,525,492).

Hill discloses a sequence that has six amino acids and comprises present SEQ ID NO: 116 (see SEQ ID NO: 14). Hills sequence would be expected to bind to the native form of the prion protein because Hills' sequence comprises present SEQ ID NO: 116.

Thus by this disclosure Hill anticipates the present claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill (US Patent 5,525,492) in view of Prusiner et al. (US Patent 5,750, 361).

Hill discloses a prion protein binding ligand comprising present SEQ ID NO: 116, as discussed above. Hill does not teach the peptide attached to the solid support.

Prusiner teaches prion protein peptides immobilized to the solid support for detection of anti-prion antibodies (see column 11, lines 45-56).

It would have been obvious to attach prion protein binding ligands to the solid support in order to use the prion protein binding ligands for detection of prion proteins in a sample.

One would have been motivated to attach prion protein binding ligands to the solid support in order to facilitate the detection of prion proteins in a detection assay.

Thus the present invention would have been *prima facie* obvious to the skilled artisan at the time the invention was made.

Claim 36, 37 and 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Venter et al. (WO 200171042-A2) in view of Prusiner et al.. (US Patent 5,750).

Verner discloses a prion protein binding ligand comprising present SEQ ID NO: 5, as discussed above. Hill does not teach the peptide attached to the solid support.

Prusiner teaches prion protein peptides immobilized to the membrane solid support for detection of anti-prion antibodies (see column 11, lines 45-56).

It would have been obvious to attach prion protein binding ligands to the solid support in order to use the prion protein binding ligands for detection of prion proteins in a sample.

One would have been motivated to attach prion protein binding ligands to the solid support in order to facilitate the detection of prion proteins in a detection assay.

Thus the present invention would have been *prima facie* obvious to the skilled artisan at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 4, 13, 14, 42 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 13-19, 36-41, 44 and 47-58 of copending Application No. 12/035,917. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application and the present claims are drawn to the prion protein binding ligands.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Double Patenting Warning

Applicant is advised that should claim 36 be found allowable, claim 45 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on Monday through Friday 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Agnieszka Boesen/
Examiner, Art Unit 1648